REMARKS/ARGUMENTS

Claims 1-4 and 8-11 are pending in the instant application. No claim amendments have been made, and a listing of the claims is included merely as a convenience for review. The specification has been amended on pages 71, 72, 75, 81, 86, and 88, to emphasize the trademark usage of the word "CELITE." Accordingly, claims 1-4 and 8-11 will remain pending upon entry of the instant amendment. *No new matter has been added.*

Moreover, amendment and/or cancellation of the claims during pendency of the application are not to be construed as acquiescence to any of the objections/rejections set forth in any Office Action, and were done solely to expedite prosecution of the application. Applicants submit that claims were not added or amended during the prosecution of the instant application for reasons related to patentability. Applicants reserve the right to pursue the claims as originally filed, subsequently amended or added, or similar claims, in this or one or more subsequent patent applications.

Objections

Arrangement of the Specification

The Examiner has directed the Applicant to the "guidelines" that illustrate "the preferred layout for the specification of a utility application." Applicants appreciate the Examiner's helpful suggestion, but respectfully remind the Examiner that these guidelines are ***suggested.*** Applicants assert that the specification for the instant application conforms to the requirements of 35 U.S.C. § 112, and therefore is suitable in its present format.

Applicants note that should a particular objection be raised, Applicants will address such objection. However, as no such objection is presently pending, Applicants assert that no action is presently necessary.

Use of Trademarks

The Examiner has indicated that the use of the trademark CELITE should be capitalized wherever it appears and be accompanied by the generic terminology. In this regard, Applicants note that the specification has been amended on pages 71, 72, 75, 81, 86, and 88, in accordance with the suggestion by the Examiner to emphasize the trademark usage of the word "CELITE." Applicants assert, however, the amendment has been restricted to the characteristics of the product known at the time the application was filed. No new matter has been added.

Rejections under 35 U.S.C. §112, First Paragraph

Rejection of Claims 8 and 11 under 35 U.S.C. §112, First Paragraph

Claims 8 and 11 stand rejected under 35 USC § 112, first paragraph. In particular, the Office Action suggests that the specification, "while being enabling for the treatment of cardiovascular disorders, does not reasonably provide enablement for the prophylaxis of cardiovascular disorders." Moreover, the Office Action suggests that "the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicants respectfully traverse this rejection.

The Office Action has analyzed the enablement of the disclosure with respect to the prophylaxis of cardiovascular disorders according to the tests described by the court in *In re Wands*. The Office Action provides specific analysis with respect to the following factors: amount of guidance provided by Applicant; unpredictability in the art; number of working examples; scope of claims; nature of the invention; and level of the skill in the art. Moreover, the analysis of the Office Action culminates by suggesting that the Applicants have not enabled the full scope of claims 8 and 11 in the absence of undue experimentation

However, Applicant respectfully reminds the Examiner, as noted in the Office Action on page 4, "[t]he test of enablement is whether one reasonably skilled in the art could make or use

the invention from the disclosures in the patent **coupled with information known in the art** without undue experimentation.[Emphasis Added]" (*United States v. Telectronics, Inc.*,857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988)). In fact, a patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). In this regard, Applicant respectfully invites the Examiner's attention to the background section, pages 1 and 2, which recite numerous examples of the state of the art at the time of filing the instant application related to Rho kinase, inhibitors thereof, and the mechanism related thereto associated with vascular musculature relaxation. Moreover, the Examiner's attention is further directed to pages 174 and 175, in which numerous examples are provided demonstrating Rho kinase activity as well as the associated vessel relaxing action of the compounds of the present invention.

Furthermore, in addition to the clear connection provided by the exemplification disclosed within the instant application and the state of the art as of the filing date of the application, Applicants assert that the blood vessel relaxing action of the compounds of the invention is useful for lowering blood pressure and increasing coronary perfusion (see page 2, lines 3-4), and therefore, would certainly be useful to treat cardiovascular disorders in a ***prophylactic*** manner. Applicants strenuously assert that at-risk patients are clearly determinable/definable from the presence of symptoms (both measurable and empirical) by the ordinarily skilled artisan without undue experimentation, and the compounds of the invention would have clear impact on the progression of the symptoms towards a cardiovascular disorder by their very nature of lowering blood pressure and increasing coronary perfusion.

For the sake of clarity, however, Applicants address the *Wands* factors, in turn:

1) Amount of guidance provided by Applicant;

The Office Action suggests that "[n]o reference is made as to how to "prevent" a cardiovascular disorder. Applicants disagree, and assert that the general comments noted herein above are directly applicable to this factor. As such, Applicants incorporate by reference the

comments above, and further emphasize that at-risk patients are clearly determinable/definable from the presence of symptoms (both measurable and empirical) by the ordinarily skilled artisan without undue experimentation, and the compounds of the invention would have clear impact on the progression of the symptoms towards a cardiovascular disorder by their very nature of lowering blood pressure and increasing coronary perfusion.

2) Unpredictability in the art

The Office Action suggests that the "use of the term 'prophylaxis' is not permitted in Claim language unless applicant can show the method is 100% effective," yet cite no authority for such a statement. Applicants disagree, and argue that such a restrictive definition is in contrast to the definition understood by the skilled artisan. Webster defines "prophylaxis" as "measures designed to preserve health (as of an individual or of society) and prevent the spread of disease." http://www.webster.com/dictionary/prophylaxis. This definition gives no explicit or implicit assertion of percentage. In fact, a measure to "preserve health" would seem to have a range of effectiveness, *e.g.*, lowering blood pressure is a measure performed to preserve health by reducing the risk of a cardiovascular disorder.

3) Number of working examples

Applicants contend that pages 174 and 175 provide sufficient evidence to enable the full scope of claims 8 and 11. In fact, Applicants respectfully remind the Examiner, that such evidence in the specification ***has been held out in the Office Action*** on page 4, as "**being enabled for the treatment of cardiovascular disorders**." (emphasis added) In particular claim 8 recites

> A method for the treatment and/or prophylaxis of cardiovascular disorders wherein a cardiovascularly effective amount of a compound as defined in claim 1 is used.

As such, by the admission of the Office Action, Applicants assert that the enabled scope of the method of treatment claim encompasses **the entire scope of compounds of claim 1**.

Applicants assert that this very same data, found sufficient to enable the method of treatment of cardiovascular disorders using a compound of claim 1, is also useful to show (in conjunction with the disclosure of the instant application and the state of the art at the time of filing) enablement for the prophylaxis of cardiovascular disorders by the very nature of their activity.

4) Scope of claims

The Office Action suggests that "the scope of the claims is very broad" based on the number of compounds that fall within the scope of the general formula (I). In this regard, Applicants argue that claim 1 has been found allowable (but for a provisional obviousness type double patenting rejection) and therefore, the Examiner has implicitly admitted that the scope of this genus of compounds is enabled. Additionally, as noted above: by the admission of the Office Action, Applicants assert that the enabled scope of the method of treatment claim encompasses **the entire scope of compounds of claim 1**.

5) Nature of the invention;

Applicants are not in disagreement with the Examiner's comments described in this factor analysis.

6) Level of the skill in the art

The Office Action suggests that the "artisan using Applicants invention would be a physician with an M.D. degree, having several years of experience." Without regard to whether Applicants agree with this assessment, Applicants would argue that such an artisan would clearly find the disclosure of the present invention in conjunction with that of the state of the art at the

time the application was filed to have sufficient enablement to use a compound of the present invention as a prophylaxis.

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Accordingly, Applicants respectfully request withdrawal of the rejection of claims 8 and 11 under 35 USC § 112, first paragraph, and favorable reconsideration.

Provisional Rejection of claims 1-4 and 8-11 under Obviousness-Type Double Patenting

Claims 1-4 and 8-11 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 8-10, and 12 of U.S. Patent Appln No. 11/547,975. Applicants assert that as the conflicting claims of Application No. 11/547,975 have not yet been patented, and as such it is not appropriate at this time to consider a terminal disclaimer. In this regard, Applicants assert that such rejection will be addressed upon allowance of the instant claims but for this rejection under obviousness-type double patenting, and in consideration of the status of the conflicting claims of Application No. 11/547,975.

Therefore, Applicants respectfully request that this rejection be held in abeyance until such time.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of all rejections, and allowance of the instantly claimed invention are earnestly solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at the telephone number below.

Applicants have filed a petition for a one-month extension of time herewith, as well as authorization to charge our Deposit Account for the related fee. Applicants believe that there are no additional fees due with this response. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 04-1105 for any fee(s) due with this response.

Dated: **December 10, 2007**

Respectfully submitted,

By_____

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